

THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Shuji Sakuma, Kiminori Atsumi and Keiichiro Kikukawa
Application No.: 10/552,541 Group Art Unit: Not Assigned
International Filing Date: February 22, 2005 Examiner: Not Assigned
Confirmation No.: 6669
Title: TRANSDERMAL AND TRANSMUCOSAL PREPARATIONS

Date: <u>12/13/06</u> EXPRESS MAIL LABEL NO. <u>EV 214897053 US</u>
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INFORMATION DISCLOSURE STATEMENT

Mail Stop PCT
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

This Information Disclosure Statement is submitted:

- ☐ under 37 CFR 1.129(a), or
(First/Second submission after Final Rejection)
- ☒ under 37 CFR 1.97(b), or
(Within any one of the following time periods: three months of filing national application (other than a CPA) or date of entry of the national stage in an international application; or before the mailing date of a first office action on the merits in a non-provisional application, including a CPA, or a Request for Continued Examination).
- ☐ under 37 CFR 1.97(c) together with either:
- ☐ a Statement under 37 CFR 1.97(e), as checked below, or
- ☐ a \$180.00 fee under 37 CFR 1.17(p), or
(After the 37 CFR 1.97(b) time period, but before final action or notice of allowance, whichever occurs first)
- ☐ under 37 CFR 1.97(d) together with:
- ☐ a Statement under 37 CFR 1.97(e), as checked below, and
- ☐ a \$180.00 fee under 37 CFR 1.17(p), or
(Filed after final action or notice of allowance, whichever occurs first, but on or before payment of the issue fee)
- ☐ under 37 CFR 1.97(i):
Applicant requests that the IDS and cited reference(s) be placed in the application file.
(Filed after payment of issue fee)

Statement Under 37 CFR 1.97(e)

- ☐ Each item of information contained in this Information Disclosure Statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Information Disclosure Statement; or
- ☐ No item of information contained in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the undersigned, after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of this Information Disclosure Statement.

Statement Under 37 CFR 1.704(d) (Patent Term Adjustment)

Applies to original applications (other than design) filed on or after May 29, 2000

- ☐ Each item of information contained in the Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart application and this communication was not received by any individual designated in § 1.56(c) more than thirty days prior to the filing of the Information Disclosure Statement.
- ☒ Enclosed herewith is form PTO-1449:
 - ☒ Copies of the cited references are enclosed. [B1-B21 and C1]
 - ☐ Copies of issued U.S. patents and published U.S. applications are not required and are not being provided.
 - ☐ Copies of the cited references are enclosed except those entered in prior application, U.S. Application No. [], to which priority under 35 U.S.C. 120 is claimed. [The earlier application contains copies of the cited references.]
 - ☒ The listed references B1-B4, B7, B11, B12, B15, B17, B19, and B21 were cited in the enclosed International Search Report in a counterpart foreign application.
 - ☒ The "concise explanation" requirement (non-English references) for reference(s) [B1-B4, B7, B11, B12, B15, B17-B21] under 37 CFR 1.98(a)(3) is satisfied by:
 - ☐ the explanation provided on the attached sheet.
 - ☐ the explanation provided in the Specification.
 - ☐ submission of the enclosed International Search Report.
 - ☐ submission of the enclosed English-language version of a foreign Search Report and/or foreign Office Action.
 - ☒ the enclosed English language abstract.

☐ Applicant requests that the following non-published pending applications be considered:

Examiner's
Initials

_____ U.S. Patent Application No. [], by [inventor(s)], filed [], Docket No.: []
_____ U.S. Patent Application No. [], by [inventor(s)], filed [], Docket No.: []
_____ U.S. Patent Application No. [], by [inventor(s)], filed [], Docket No.: []

Examiner

Date

- ☐ A copy of each above-cited application, including the current claims, is enclosed, except any application filed on or after June 30, 2003, which has been scanned into the PTO's Image File Wrapper (IFW) system and is available to the examiner.
- ☐ A copy of each above-cited application, including the current claims, is enclosed, except those entered in prior application, U.S. Application No. [], to which priority under 35 U.S.C. 120 is claimed.

The Examiner is requested to return a copy of the above list of pending applications indicating which references were considered with the next office communication.

It is requested that the information disclosed herein be made of record in this application.

Method of payment:

- ☐ A check for the fee noted above is enclosed, or the fee has been included in the check with the accompanying Reply. A copy of this Statement is enclosed.
- ☐ Please charge Deposit Account 08-0380 in the amount of \$[]. A copy of this Statement is enclosed.
- ☒ Please charge any deficiency in fees and credit any overpayment to Deposit Account 08-0380.

Respectfully submitted,

HAMILTON, BROOK, SMITH & REYNOLDS, P.C.

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Dated: Dec. 13, 2006

PTO-1449 REPRODUCED INFORMATION DISCLOSURE STATEMENT IN AN APPLICATION December 13, 2006 (Use several sheets if necessary)	ATTORNEY DOCKET NO. 3462.1016-000		APPLICATION NO. 10/552,541	
	FIRST NAMED INVENTOR Shuji Sakuma		INTERNATIONAL FILING DATE February 22, 2005	
	EXAMINER		CONFIRMATION NO. 6669	GROUP

FOREIGN PATENT DOCUMENTS						
		DOCUMENT NUMBER Country Code-Number-Kind Code (if known)	DATE MM-DD-YYYY	NAME OF PATENTEE OR APPLICANT OF CITED DOCUMENT	TRANSLATION YES NO	
	B1	JP 63-27414 A	02-05-1988	Shiseido Company Ltd.		X
	B2	JP 63-107938 A	05-12-1988	SANGI KK		X
	B3	JP 63-188628 A	08-04-1988	Shiseido Company Ltd.		X
	B4	JP 4-507106 A	12-10-1992	President and Fellows of Harvard College		X
	B5	JP 5-178762 A	07-20-1993	Sekisui Chem Co. Ltd.	X	
	B6	JP 5-238956 A	09-17-1993	Koyama Yoshiyuki Unitika Ltd.	X	
	B7	JP 5-255095 A	10-05-1993	ADVANCE KK; AOKI H		X
	B8	JP 6-256218 A	09-13-1994	Lederle Japan Ltd.	X	
	B9	JP 7-2689 A	01-06-1995	Advanced Sukin Res Kenkyusho KK	X	
	B10	JP 7-101864 A	04-18-1995	Sekisui Chem Co Ltd.	X	
	B11	JP 7-165613 A	06-27-1995	Dott Research Laboratory		X
	B12	JP 8-27031 A	01-30-1996	Dott Research Laboratory		X
	B13	JP 9-118636 A	05-06-1997	Kanebo Ltd.	X	
	B14	JP 10-95738 A	04-14-1998	T T S Gijutsu Kenkyusho KK	X	
	B15	WO 98/18339 A	05-07-1998	AOKI, Hideki		X
	B16	JP 11-80031 A	03-23-1999	Sekisui Chem Co Ltd.	X	
	B17	JP 2001-48865 A	02-20-2001	Takeda Chemical Industries, Ltd.		X
	B18	JP 3417744 B2	04-11-2003	Kanebo Ltd.		X
	B19	JP 2003-250454 A	09-09-2003	Lion Corp.		X
	B20	JP 3471840 B2	09-12-2003	Lederle Japan Ltd.		X
	B21	JP 2004-75662 A	03-11-2004	Mook Co., Ltd.		X
OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)						
	C1	Takahashi, et al., <i>Jpn J Clin Pharmacol Ther (Rinsho Yakuri)</i> , 23(1): 343-344 (1992).				

EXAMINER	DATE CONSIDERED
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